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Challenge TB - Ukraine
Year 2
Annual Report
October 1, 2015 – September 30, 2016

October 30, 2016

Cover photo: MDR TB patient holds a new passport which he has never had for the last 15 years - issued thanks to the legal assistance provided by the lawyer and social worker of the Charitable Fund “Vykhid” (Way Out) within the Challenge TB project in Mykolaiv, Ukraine”. The passport allows to receive full range of treatment.

Credit: Olena Goryacheva

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List of Abbreviations and Acronyms

ADR	adverse reactions to drugs
AIDS	acquired immune deficiency syndrome
APA	Annual Plan of Activities
BDQ	bedaquiline
CCM	National Coordination Council
CSW	commercial sex worker
CTB	Challenge TB
DOT	directly observed treatment
GLC	Green Light Committee
HIV	human immunodeficiency virus
IC	infection control
IDU	injection drug users
IRB	Institutional Review Board
KNCV	KNCV Tuberculosis Foundation
M&E	monitoring and evaluation
MARP	most-at-risk population
MOH	Ministry of Health
MDR-TB	multidrug-resistant tuberculosis
MSM	men who have sex with men
NGO	nongovernmental organization
NTP	national tuberculosis program
OR	operational research
PLHIV	people living with HIV/AIDS
PMU	Project Management Unit
SES	Sanitary – Epidemiological Services
SOP	standard operational procedure
TB	tuberculosis
TB Institute	Yanovsky National Institute of TB and Pulmonology of Academy of Medical Science
UCDC	Ukrainian Center for Socially Dangerous Disease Control
USAID	United States Agency for International Development
WHO	World Health Organization
XDR-TB	extremely drug-resistant tuberculosis

1. Executive Summary

This report covers the Challenge TB (CTB) project's progress and achievements during the project Year 2 (October 1, 2015 – September 30, 2016). During the reporting period, PATH collaborated with KNCV Tuberculosis Foundation (KNCV), the United States Agency for International Development (USAID), the Ministry of Health (MOH) of Ukraine, the Ukrainian Center for Socially Dangerous Disease Control (UCDC, implements national tuberculosis program [NTP] functions and recently transformed into the National Public Health Center), Yanovsky National Institute of TB and Pulmonology of Academy of Medical Science (TB Institute), and other partners at the national level, and with the oblast health departments, oblast branches of National Red Cross Society, and partners from Poltavaska, Mykolayivska, and Kyivska oblasts to implement the Year 2 work plan. In this period, the project continued to expand and improve a model for a patient-centered approach to multidrug-resistant tuberculosis (MDR-TB) care based on high-quality ambulatory treatment and other MDR-TB control services. Specifically, the project extended patient-centered approach activities to a new project partner oblast (Kyivska oblast); developed recommendations on improving the process of active case-finding and management of TB among close contacts; developed the draft Implementation Protocol on New Drugs Introduction and preliminary version of an operational research (OR) protocol for introducing shortened treatment regimens for MDR-TB treatment; and laid groundwork for the protocol's implementation in the selected site (Kyivska oblast), with the aim of achieving the project's objective of improved MDR-TB treatment success rates (TSR) in project oblasts. These contribute to the following end-of-project achievements:

- Patient centered care for MDR TB patients focused on outpatient model is routinely used in CTB supported areas by 2019, increasing the treatment success rate by 10%.
 - At least 2000 eligible MDR TB patients will be initiated on a shorter MDR TB treatment regimen and regimens with new drugs.
- In Year 2, the draft clinical guidelines for side effects management for TB and MDR-TB patients were developed and submitted to the UCDC and the State Expert Center for further approval by the MOH for countrywide implementation. To enhance the capacity of TB and primary health care providers in side effects management, two workshops in guidelines principles were conducted for 56 participants, who developed regionally specific models of the multidisciplinary patient-oriented approach to side effects management for further implementation in the project regions. To enhance monitoring and prevention of adverse reactions (ADR) among patients being treated for MDR-TB, limited procurement of laboratory supplies as well as audiometers to diagnose and quantify the degree of hearing loss were procured within CTB in Year 2. To further implement clinical guidelines over the whole country, PATH initiated a series of all-Ukrainian webinars on various topics as an efficient way of information sharing that allowed all TB and other interested providers in Ukraine to participate. Two webinars on guidelines principles and the pharmacovigilance system in

Ukraine were conducted in collaboration with the National TB Institute and the State Expert Center of the MOH. More than 200 participants from 23 oblasts in Ukraine took part in the webinars. The audience was presented with a brief overview of the clinical guidelines and pharmacovigilance system in Ukraine. A number of side effects management cases were also presented to the audience, as had been highly requested by TB doctors for use during DR-TB case management. Analysis of e-TB manager data from CTB Project oblasts demonstrates gradual improvement of ADR reporting, although it is not yet good enough (e.g., in Poltavskya oblast, the proportion of patients on MDR-TB treatment who reported ADR increased gradually from 12 to 39 percent during the reporting period).

- During the reporting period, the CTB project developed two documents on introducing new drugs and shorter drug regimens for the treatment of MDR-TB and XDR-TB (extremely drug-resistant TB): a draft protocol on implementation of new drugs in MDR-TB treatment called “On Approval of the Clinical Protocol for Treatment of Adult Patients with Multidrug-Resistant Tuberculosis Under Individualized Chemotherapy Regimens Using New TB Drugs (Bedaquiline, Delamanid) Obtained Through International Technical Assistance Projects” and a preliminary version of an operational research (OR) protocol on the shortened treatment regimens for MDR-TB patients. These documents were developed in close collaboration with the National TB Institute and UCDC. Because new drugs and regimens are not registered or included into the national programmatic guidelines, it is necessary for CTB to perform intensive advocacy work to get MOH approval of the protocol on new drugs implementation. As part of this effort, the project collected reviews of suggested pre-XDR/XDR treatment regimens and enrollment/exclusion criteria based on international evidence and recommendations from the World Health Organization (WHO)-Ukraine, WHO-Euro, KNCV, and USAID, taking into consideration the local situation (DR-survey results, access to tests, available drugs, etc.). Currently, the implementation protocol is being reviewed by in-country stakeholders, PMU, and USAID and will be adjusted according to the recommendations. Also, based on intensive discussions with providers from Kyivska oblast (the proposed site for implementation of the operational research), a set of required standard operational procedures (SOPs) was developed, including MDR/XDR-TB case detection at different levels of care, pharmacovigilance, patient monitoring, and other key elements. During the reporting period, nine draft SOPs were drafted. Key next steps include providing assistance to NTP in developing the bedaquiline (BDQ) donation request, identifying the best approach to assure supply, calculating the number of patients involved, providing technical assistance to Kyivska oblast to improve utilization of existing resources, finalizing training providers in MDR-TB case management, ensuring the quality of the laboratory diagnostics, strengthening TB case management at the ambulatory stage, and ensuring proper monitoring. Enrollment of patients is expected to start in Quarter 2 of APA3.

The OR protocol on shortened treatment regimens for MDR-TB patients was developed with consideration of the lack of clofazimine in the country (not registered and not available). A

team of Ukrainian and KNCV experts adjusted the recommended WHO treatment regimen and submitted it for review to WHO and GLC. Additional information requested by GLC will be provided in APA3. After GLC response, key next steps will include submitting the protocol for ethical review to the Kyivska oblast ethical committee, the National TB Institute's Ethical Board, and PATH's Institutional Review Board (IRB), and conducting an introductory workshop.

- To ensure timely detection, diagnosis, and treatment initiation for potentially missed TB cases, the CTB project developed and pretested a draft algorithm of contact investigation and the roles of TB services, (Sanitary – Epidemiology Station) SES, and primary health care level in TB contact investigation and management. The project also finalized the set of recommendations for the national contact investigation strategy to be adopted by the NTP. As the result, during three months of implementation the average number of detected contacts increased by 40 – 50 % in project oblasts and reached 2,8 – 3,2 contacts per one MDR TB case.
- In the reporting period, the CTB project has continued to implement the patient-centered approach and had developed, introduced, and implemented the patient-centered strategy on provision of medical, social, and psychological support for MDR-TB patients in Poltavaska and Mykolaivska oblasts based on ambulatory treatment. The comprehensive package of guiding documents was developed to build capacity of health care and social service providers in the strategy implementation. The package consists of three documents: MDR-TB Ambulatory Care Model, Patient-Centered Psychosocial Support Strategy, and Roadmap for Implementation of Patient-Centered Care During MDR-TB Treatment. This package was introduced at the National TB Conference and was highly valued by participants from all oblasts. CTB conducted **seven** trainings and workshops on the patient-centered approach, interpersonal communication and counseling, psychosocial support, and treatment adherence. More than **150** TB doctors, directly observed treatment (DOT) curators, nurses of TB and primary health care facilities, Red Cross visiting nurses, social workers, and psychologists from the partnering nongovernmental organizations (NGOs) participated in these training events and enhanced their capacity to provide timely and quality patient-centered support to MDR/XDR-TB patients during the outpatient phase of treatment. The efficiency of social and psychosocial support provided within CTB has been evaluated based on the results of systematic monitoring and evaluation. A comprehensive care package of psychosocial support was provided to **311** MDR-TB patients to ensure sustainable treatment adherence and reduction of default rates. More than three-quarters (76.8 percent) of patients (**239** out of **311**) who enrolled in the patient-centered support in Year 2 currently continue their treatment, and **39** patients (12.5 percent) have successfully completed treatment so far. Only **6** patients (1.9 percent) were lost to follow-up, and **16** patients (6.4 percent) interrupted their treatment for less than one month but thanks to the timely provided support within CTB, restarted treatment and currently continue it; these preliminary results seem to be much better compared with national 2013 MDR-TB cohort data showing 18% lost to follow up. CTB will continue

providing psychosocial support to enrolled patients in APA3 to evaluate the increase of the MDR-TB treatment efficacy as the majority of enrolled patients continue their treatment. The project will roll out this activity to new project oblasts in APA3 according to the APA3 plan.

2. Introduction

With USAID funding through Challenge TB, PATH continued to collaborate with KNCV Tuberculosis Foundation (KNCV), USAID, the MOH of Ukraine, the TB Institute, and UCDC at the national level, and with health departments and partners from Poltavaska, Mykolayivska, and Kyivska oblasts to provide support to the NTP and oblast TB programs in further strengthening interventions and capacity to control TB and MDR-TB and provide support and technical assistance to partner oblasts in the integration of a patient-centered approach based on the ambulatory health care model into oblasts' routine MDR-TB case management system, with the aim of achieving the project's objective of improved MDR-TB treatment success rates in project oblasts.

The goal of the project is to improve outcomes for MDR-TB patients by reducing mortality, lowering default rates, improving MDR-TB case detection and diagnosis, and enhancing treatment success. The achievement of this goal requires targeted efforts to address MDR-TB, as well as crosscutting activities aimed at strengthening NTP capacity and systems and using innovative approaches to improve TB services in Ukraine, including introduction of the new drugs and regimens.

The project is implemented at the national level and at the oblast level in three oblasts (Poltavska, Mykolayivska, and Kyivska), covering a total population of 4,328,219 (10% of total population).

Figure 1. Map of Ukraine.



During 2016, PATH and KNCV provided technical assistance and support to the MOH and its partners toward the following objectives:

Improve enabling environment through implementation of a pilot model of ambulatory care for MDR-TB patients based on a patient-centered approach considering different local conditions (rural vs. urban, vulnerable populations, etc.) and different patients' preferences in project oblasts and providing technical assistance to the NTP in scaling up of the piloted model to other oblasts of Ukraine. The purpose of ambulatory care for MDR-TB is to maximize the benefits to the patient while minimizing the costs to both the patient and the health care system—thus improving treatment outcomes.

Ensure patient-centered care and treatment through advocacy to health care authorities in project sites for expanding TB services to ambulatory primary health care with the correspondent shifting of resources, emphasizing the advantages of ambulatory care, which include a decrease in costs related to hospitalization, a reduced risk of ongoing TB transmission to other patients and health care staff within facilities, and an increase in patient autonomy and satisfaction (leading to greater completion of treatment and decreases in loss to follow-up).

The project led development of a patient-support strategy based on assessment of patients' needs and with engagement of all local partners to ensure a patient-centered approach in MDR-TB case management to address structural barriers to treatment adherence. The project ensured linkage to support services as needed, especially for MDR-TB patients with HIV comorbidity or who are/ have misused alcohol or drug, were released from prison, and are homeless. It identified and implemented mechanisms for ongoing patient support to address conditions that threaten their ability to complete treatment through the involvement of Red Cross visiting nurses, human immunodeficiency virus (HIV) service organizations, and other social resources. To ensure the quality of support services, capacity-building of local NGOs was also implemented and consistent monitoring of services conducted.

The project assessed and strengthened the system of active case finding among close contacts of MDR-TB patients to ensure timely diagnosis and treatment initiation for potentially missed TB cases.

To ensure delivery of an adequate regimen of quality-assured medications as well as monitoring and proper treatment of side effects or adverse reactions to drugs, the project developed guidelines for side-effect management, built providers' capacity through direct trainings and webinars, and assisted in establishing an on-the-job supervision system to mentor and support the providers. The project also helped oblasts to improve the quality of laboratory diagnosis of side effects and to strengthen their capacity in monitoring and evaluation (M&E) of MDR-TB program implementation.

To ensure enhanced treatment outcomes and reduced mortality of MDR-TB patients, the project advocated for introducing new drugs and shorter drug regimens for the treatment of MDR-TB and XDR-TB, developed draft protocols to be approved by the country authorities,

built capacity of providers to introduce new drugs in Kyivska oblast, and continued strong communication with national and international stakeholders to prompt passage of the required approvals, start treatment, and scale it up to other regions of Ukraine.

The project worked with NTP, TB Institute, WHO, and other stakeholders to introduce shorter regimens for treatment of DR-TB through operational research. Results will lead to the development of national recommendations for broader national TB control program use in the country.

Strengthen infection control (IC) to ensure compliance with proper IC measures in all health care settings and in the community, providing assistance in project oblasts in implementing the developed facility and oblast IC plans, developing information materials, and procuring a limited amount of essential IC equipment.

Enhance political commitment and leadership to ensure sustainability of effective TB-related interventions at the national and oblast levels. The project seeks to enable the government of Ukraine to make critical, technically sound policy and program decisions to improve TB and MDR-TB control in accordance with international best practices and will provide technical assistance to the development of the next national TB strategic plan (program) for 2017–2021 based on the WHO NTP review conducted in April 2015. At the request of the NTP, two project staff worked in the working groups on draft program development.

Address human resource development and strengthen the capacity of total 219 (160F/59M) TB and primary health care providers at the oblast level in MDR-TB case management through trainings, webinars, and on-the-job mentoring. To ensure effective scaling up of the activities piloted and conducted in the project sites, the CTB project organized a joint national dissemination meeting with NTP, WHO, and other USAID-funded TB projects with participation of non-project oblasts.

3. Country Achievements by Objective/Sub-Objective

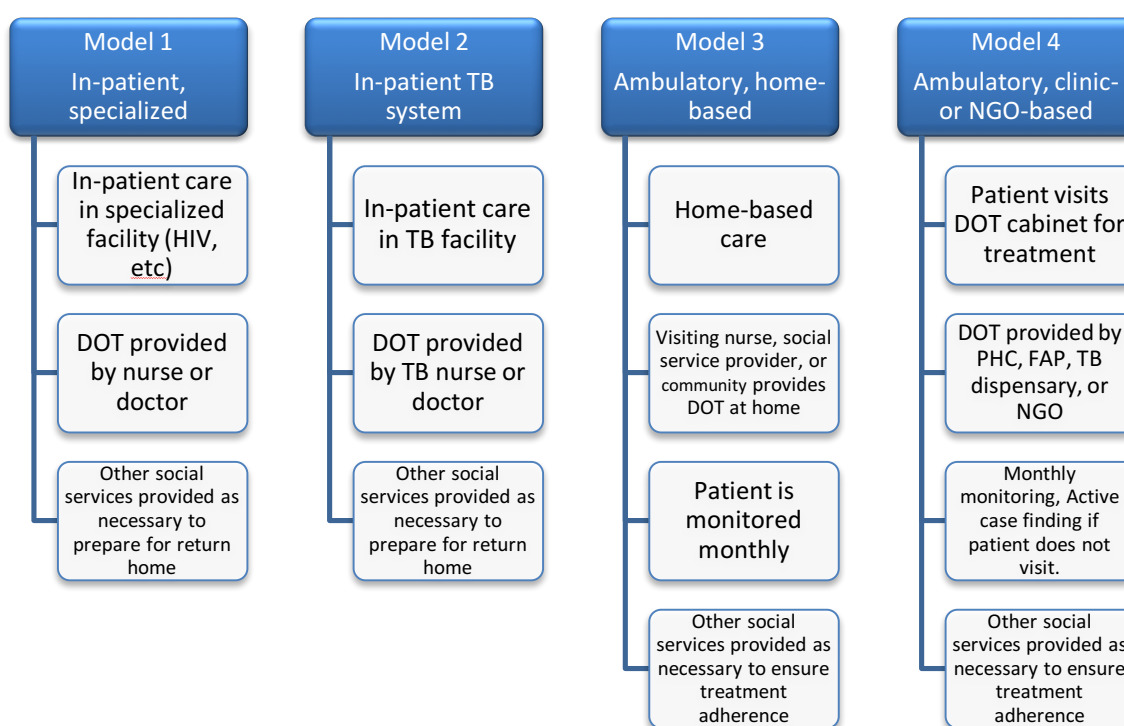
Objective 1. Improved Access

Sub-objective 1. Enabling environment

According to the APA2 Plan, CTB team in collaboration with USAID Mission, NTP and TB Institute developed criteria, discussed and selected Kyivska oblast as a new site for project implementation with specific focus on the new drugs introduction. The assessment mission to Kyivska oblast was conducted in April to assess existing services for MDR-TB diagnosis, inpatient and outpatient treatment, political commitment to participate in the CTB project and preparedness for introduction of the new drugs and regimens. Based on assessment results the capacity building plan was developed and implemented during third and fourth quarters of 2016.

During the reporting period, the project developed a model for a patient-centered approach to MDR-TB care, based on ambulatory treatment and quality improvement of MDR-TB control services, with the aim of achieving the project's objective of improved MDR-TB treatment success rates in project oblasts.

Figure 2. Patient-centered TB care models.



The goal of creating a system of ambulatory care for MDR-TB is to maximize the benefits to the patient, while minimizing the costs to both the patient and the health care system. Ambulatory care should be used as one tool within a larger constellation of activities to increase treatment success and reduce the burden of MDR-TB in Ukraine. PATH engaged all possible service providers at

the ground level, including primary health care providers, Ukrainian Red Cross Society (URCS) and other NGOs in developing the ambulatory care algorithm. The developed model is designed to be used as a handout for physicians and patients to discuss treatment opportunities and develop a plan. The model includes the general treatment approach and an ambulatory care algorithm based on existing primary health care possibilities. The model was approved by Orders in Poltavaska and Mykolaivska oblasts. PATH introduced the model to the UCDC and other national stakeholders and partners to be used as the base for the national outpatient TB health care model.

#	Outcome Indicators	Indicator Definition	Baseline (Year/ timeframe)	Target	Result
				Y2	Y2
1.4.1	One or more components of the patient-centered approach are adopted into routine practice/policy	Description: One or more components of the patient-centered approach (i.e. universal access, consider patient needs, respect rights, provide quality care, establish trust, participate in process, and empower involvement) are adopted into routine practice/ policy. Indicator Value: Yes/No. Level: National.	2	3	3 Consider patient needs, provide quality care, establish trust
1.4.8	UKRAINE SPECIFIC: Algorithm of MDR-TB out-patient case management developed		Yes (in 1 site)	Yes (in 2 sites)	Yes (in 2 sites)

Sub-objective 3. Patient-centered care and treatment

During the reporting period, CTB conducted an assessment of the current system of contact investigation, which revealed a fragmented, inconsistent, and ineffective system that requires improvements. To ensure timely diagnosis and treatment initiation for potentially missed TB cases, the CTB project conducted 2 roundtable meetings at project sites with participation of the NTP representative and all involved parties to review existing practices, discuss barriers, challenges, gaps, and needs in TB contacts investigation and management. A set of recommendations was drafted to be included in the contact investigation algorithm. The most significant challenges in TB contacts investigation and management are: the current decline of the Sanitary – Epidemiological Services (SES), which used to play a central role in contacts investigation and management; the lack of holistic guidelines on TB contact investigation and management; and the lack of current, approved guidelines in pediatric TB management.

To build understanding and capacity of providers two seminars were conducted in Poltavaska and Mykolayivska oblasts.

The contact investigation algorithm was developed based on the assessment and recommendations. To pretest and implement developed recommendations the CTB project conducted a workshops in Poltava and Mykolayiv with all involved parties to discuss a developed draft algorithm and the roles of TB services, SES, and primary health care level in TB contact investigation and management. During the last quarter of the year, the CTB project supported the implementation of a holistic, consistent system of contact investigation and followed-up in Mykolayivska and Poltavaska oblasts. As the result, the average number of detected contacts increased by 40 – 50 % in project oblasts and reached 2,8 – 3,2 contacts per one MDR TB case, which is still relatively low.

The project also finalized the set of recommendations to be suggested to the national contact investigation strategy. In APA3 the CTB will provide TA to NTP on adoption of the developed recommendations.

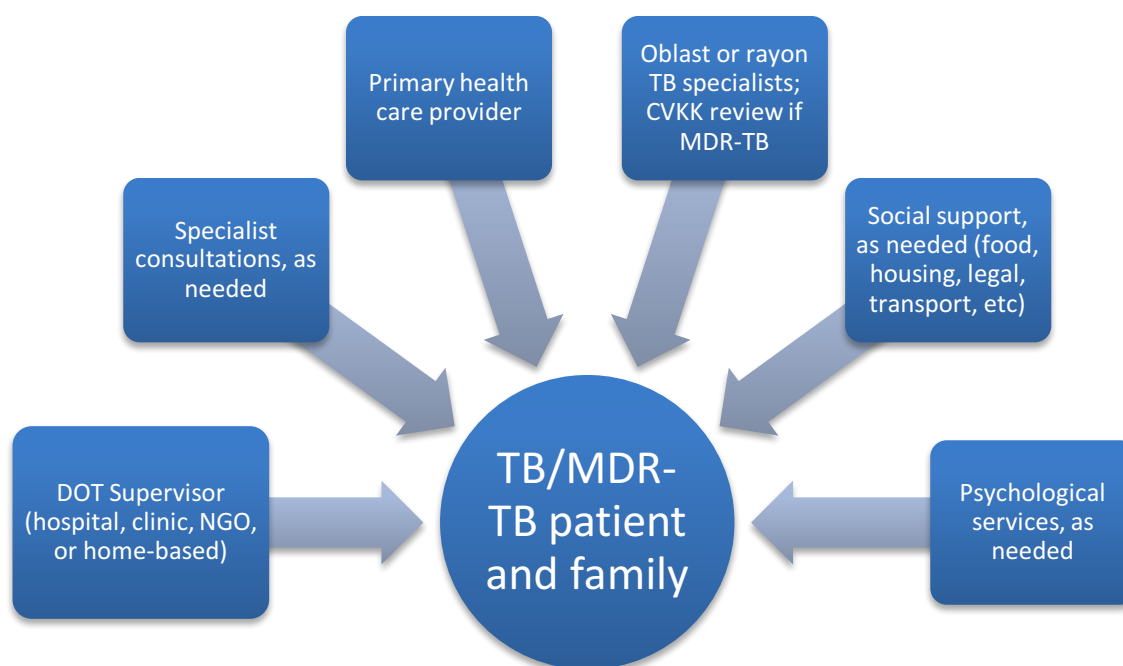
Intervention area 3.2. Access to quality treatment and care ensured for TB, DR TB and TB/HIV for all risk groups from all care providers

3.2.1. Provide support to MDR-TB patients to ensure patient centered approach in MDR -TB care:

MDR-TB patients face many psychological, social and economic difficulties due to the long duration of treatment, adverse drug reactions, stigma, and financial burden that contribute to decreasing adherence to treatment and unsuccessful treatment outcomes. Any of these problems, that MDR-TB patients face, complicate clinical management of the patients and negatively affect their quality of life. Knowing patients' needs and providing constant support to them and their families, being responsive to their preferences, needs and values, in other words, providing patient-centered care is crucial to achieving better treatment results.

To meet this goal, the CTB project continued to implement the patient-centered approach and had developed, introduced, and implemented the patient-centered strategy on provision of medical, social, and psychological support for MDR-TB patients in Poltavaska and Mykolaivska oblasts based on ambulatory treatment.

Figure 3. Patient-centered care.



The comprehensive set of guiding documents was developed to build capacity of health care and social service providers in the strategy implementation. The set consists of three documents: MDR-TB Ambulatory Care Model, Patient-Centered Psychosocial Support Strategy, and Roadmap for Implementation of Patient-Centered Care During MDR-TB Treatment. This package was introduced at the National TB Conference and was highly valued by participants from all oblasts.

To provide ongoing medical, psychosocial, social, and other support to MDR-TB patients in need at the ambulatory phase of treatment, the project team chose five local community-based organizations (CBOs) in two project regions that provided patient-centered interventions. In addition, considering conditions that threaten the patients' ability to complete treatment, the Red Cross visiting nurses ensured DOT at home to prevent loss to follow-up.

CTB conducted **seven** trainings and workshops on the patient-centered approach, interpersonal communication and counseling, psychosocial support, and treatment adherence. More than **150** TB doctors, DOT curators, nurses of TB and primary health care facilities, Red Cross visiting nurses, social workers, and psychologists from the partnering nongovernmental organizations (NGOs) participated in these training events and enhanced their capacity to provide timely and quality patient-centered support to MDR/XDR-TB patients during the outpatient phase of treatment.

The efficiency of social and psychosocial support provided within CTB has been assessed based on the results of systematic monitoring and evaluation.

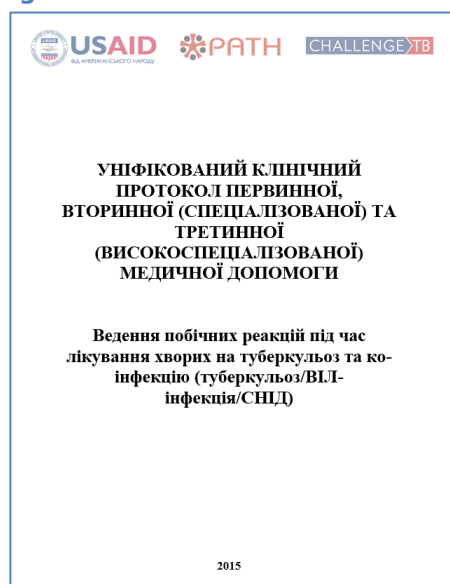
A comprehensive care package of psychosocial support was provided to **311** MDR-TB patients to ensure sustainable treatment adherence and reduction of default rates. As a result of the patient-

strategy implementation, three-quarters (76.8 percent) of patients (**239** out of **311**) who enrolled in the patient-centered support in Year 2 currently continue their treatment, and **39** patients (12.5 percent) have successfully completed treatment so far. Only six patients (1.9 percent) were lost to follow-up despite the provided psychosocial support, and **16** patients (6.4 percent) interrupted their treatment for less than one month but thanks to the timely provided support within CTB, restarted treatment and currently continue it. CTB will continue providing psychosocial support to enrolled patients in APA3 to evaluate the increase of the MDR-TB treatment efficacy as the majority of enrolled patients continue their treatment. The project will roll out this activity to three new project oblasts in APA3 according to the APA3 plan.

3.2.3. Implementation of clinical guideline for side-effects management for TB, DR-TB patients:

In Year 2, the draft clinical guidelines for side effects management for TB and MDR-TB patients were developed and submitted to the Ukrainian CDC and the State Expert Center for further approval by the MoH for countrywide implementation. To enhance capacity of TB and primary health care providers in side effects management, two (2) workshops in guideline principles were conducted for 56 participants who developed the regionally specific models of multi-disciplinary patient-oriented approach to the side effects management for further implementation in the project regions. With the National TB Institute participation, two (2) mentoring visits including on-the-

Figure 4. ADRs management guidelines.



job training events were conducted to Poltavaska and Mykolaivska oblasts. The mentoring team visited the TB and primary health care facilities, participated in the Central Medical Counseling Committee (CMCC) meeting, reviewed more than 70 medical record books of MDR-TB patients highlighting the side effects registration and treatment cases as well as provided on-the-job training on side effects management principles. The mentoring visits findings and recommendations were sent to the oblast TB service for consideration and improvement of registration of side effects in eTB-Manager. To enhance the adverse reactions (ADR) monitoring and prevention among patients being treated for MDR-TB, limited procurement of laboratory supplies as well as audiometers for evaluating the level of hearing to diagnose and quantify the degree of hearing loss were procured within CTB in Year 2. Analysis of e-TB manger data from CTB

Project oblasts demonstrates gradual improvement of ADR reporting, though not yet good enough (e.g. in Poltavaska oblast the proportion of patients on MDR- TB treatment reported the ADR increased gradually from 12% average to 39% during the reporting period).

To further implement clinical guidelines all over Ukraine, PATH initiated a series of all-Ukrainian webinars on various topics as an efficient way of information sharing that allowed all TB and other interested providers in Ukraine to participate. Two webinars on guidelines principles and pharmacovigilance system in Ukraine were conducted in collaboration with the National TB Institute and the State Expert Center of MoH. More than 200 participants from 23 oblasts in Ukraine took part in the webinars. The audience was presented with a brief overview of the clinical guidelines and pharmacovigilance system in Ukraine. A number of side effects management cases were also presented to the audience that was highly requested by TB doctors for usage during the DR TB case management. The participation profile represented significant interest of care providers at all levels and included chief doctors, deputy chief doctors, MDR-TB department heads of oblast and district TB dispensaries, rayon/district TB doctors working in the primary health care service, and representatives from UCDC, the National Research Institute on TB and Lung Diseases, and the National Medical University. We received positive feedback from the participants, who emphasized that the developed clinical guidelines were in high demand by TB doctors for proper DR-TB case management.

3.2.6. Assessment of the M/XDR-TB situation, preparedness of the NTP for implementation of shortened regimens and new drugs:

During the reporting period, the CTB project conducted an assessment of the readiness and capability of the national TB program to implement new treatment approaches, including new drugs and shorter drug regimens for drug-resistant TB (DR-TB) treatment. Considering the high importance and innovation of this new activity, the joint KNCV–PATH team discussed with national professionals the flow of information, reviewed the national data collection tools and available data, including estimated numbers of DR-TB patients eligible for shortened regimens and in need of regimens containing new drugs, and assessed the existing clinical pathways and access to DR-TB diagnosis and treatment for adults and children. The implementation oblast (Kyivska) was preliminarily selected and submitted for approval to the USAID Mission. An assessment visit to the e-TB Manger registry, clinical, and laboratory facilities in Kyivska oblast's tuberculosis dispensary (TD) was conducted.

As a result, the assessment team concluded that despite small gaps, the overall readiness of Ukraine's TB program to introduce new treatment approaches is appropriate. The following recommendations and next steps were developed, including creating an operation research (OR) protocol; conducting an introductory workshop; calculating the number of patients involved; designing the shortened and pre-XDR/XDR treatment regimens and enrollment/exclusion criteria based on international evidence/recommendations; taking into consideration the local situation (DR-survey results, access to tests, available drugs, etc.); and “preparing the ground”—that is, providing technical assistance to Kyivska oblast to improve utilization of existing resources.

3.2.7. Development of operational research protocols for introduction of shortened MDR-TB treatment regimens and regimens containing new drugs:

During the reporting period, the CTB project developed two documents on introducing new drugs and shorter drug regimens for the treatment of MDR-TB and XDR-TB (extremely drug-resistant

Figure 5. NDR and shorter treatment regimens discussion with Kyivska oblast.



TB): a draft protocol on implementation of new drugs in MDR-TB treatment called “On Approval of the Clinical Protocol for Treatment of Adult Patients with Multidrug-Resistant Tuberculosis Under Individualized Chemotherapy Regimens Using New TB Drugs (Bedaquiline, Delamanid) Obtained Through International Technical Assistance Projects” and a preliminary version of an operational research (OR) protocol on the shortened treatment regimens for MDR-TB patients.

These documents were developed in close collaboration with the National TB Institute and UCDC. Because new drugs and

regimens are not registered or included into the national programmatic guidelines, it is necessary for CTB to perform intensive advocacy work to get MOH approval of the protocol on new drugs implementation. As part of this effort, the project collected reviews of suggested pre-XDR/XDR treatment regimens and enrollment/exclusion criteria based on international evidence and recommendations, taking into consideration the local situation (DR-survey results, access to tests, available drugs, etc.) from the World Health Organization (WHO)-Ukraine, WHO-Euro, Project Management Unit (PMU), and USAID. Currently, the implementation protocol is being reviewed by in-country stakeholders, PMU, and USAID and will be adjusted according to the recommendations. Also, based on intensive discussions with providers from Kyivska oblast (the proposed site for implementation of the operational research), the set of required standard operational procedures (SOPs) was developed, including MDR/XDR-TB case detection at different levels of care, pharmacovigilance, patient monitoring, and other key elements. During the reporting period, nine SOPs were drafted. Key next steps include providing assistance to NTP in developing the bedaquiline (BDQ) donation request, identifying the best approach to assure supply, calculating the number of patients involved, providing technical assistance to Kyivska oblast to improve utilization of existing resources, finalizing training providers in MDR-TB case management, ensuring the quality of the laboratory diagnostics, strengthening TB case management at the ambulatory stage, and ensuring proper monitoring. Enrollment of patients is expected to start in Quarter 2 of APA3.

The OR protocol on shortened treatment regimens for MDR-TB patients was developed with the consideration of lack of clofazimine in the country (not registered and not available). Team of Ukrainian and KNCV experts adjusted the recommended WHO treatment regimen and submitted it for the review to WHO and GLC. Additional information requested by GLC will be provided in APA3. After GLC response, key next steps will include submitting the protocol for ethical review to the Kyivska oblast ethical committee, the National TB Institute's Ethical Board, and PATH's Institutional Review Board (IRB), and conducting an introductory workshop.

#	Outcome Indicators	Indicator Definition	Baseline (Year/ timeframe)	Target	Result
				Y2	Y
3.1.1	Number and percent of cases notified by setting (i.e. private sector, pharmacies, prisons, etc.) and/or population (i.e. gender, children, miners, urban slums, etc.) and/or case finding approach	Description: The number of TB cases all forms (i.e. bacteriologically confirmed plus clinically diagnosed, new and relapse) reported by the NTP disaggregated by setting (i.e. private sector, pharmacies, prisons, etc.) and/or population (i.e., gender, children, miners, urban slums, etc.) and/or case finding approach (ICF, ACF, CI). Private sector providers should be described according to context and case finding approach, for example, type of provider targeted (i.e. ,for profit medical clinics, pharmacists, informal providers, private hospitals, etc.). Indicator Value: Number and where available, percent. Level: National and Challenge TB geographic areas. Numerator: Number of TB cases all forms (bacteriologically confirmed + clinically diagnosed; includes new and relapse cases) reported (by setting/ population/ case finding approach) nationally and in Challenge TB geographic areas in the past year. Denominator: Total number of TB cases (all forms) notified nationally and in Challenge TB geographic areas.	Poltavska obl – 1,043 (3 among contacts), Mykolayivska obl- 936 (9 among contacts) (2014, NTP)	Poltavska obl - 5 among contacts Mykolayivska obl - 12 among contacts	Poltavska obl – 1,113 (3 (0.3%) among contacts) Mykolayivska obl- 1,277 (9 (0.7%) among contacts)
3.1.4	Number of MDR-TB cases detected	Description: Total number of bacteriologically confirmed MDR-TB cases diagnosed. Project should follow the MDR-TB/Xpert algorithm in country regarding whether Rifampicin-resistant TB cases (RR-TB) should be counted as confirmed MDR-TB. If a country's algorithm states that a RR-TB cases is automatically assumed to be MDR-TB (i.e. no further DST required),	Poltavska obl - 414, Mykolayivska obl - 360 (2014, NTP)	Poltavska obl - 370, Mykolayivska obl - 400	Poltavska oblast: 267 Mykolayivska oblast: 505 (Oct–Sept 2016)

		<p>then RR-TB should be included in the number of confirmed MDR-TB cases diagnosed. Otherwise, RR-TB should be excluded until proven via further DST that the case is a confirmed MDR-TB case.</p> <p>Indicator Value: Number.</p> <p>Level: National and Challenge TB geographic areas.</p> <p>Numerator: Number of bacteriologically confirmed MDR-TB cases diagnosed during the reporting period.</p>			
3. 2. 4	Number of MDR-TB cases initiating second-line treatment	<p>Description: The number of bacteriologically confirmed, clinically diagnosed or unconfirmed MDR-TB cases started on second-line treatment during the reporting period. Unconfirmed MDR-TB cases are those awaiting C/DST results. RR-TB may fall under confirmed or unconfirmed depending on the country's MDR-TB diagnosis algorithm.</p> <p>Indicator Value: Number.</p> <p>Level: National and Challenge TB geographic areas.</p> <p>Numerator: The number of confirmed or unconfirmed MDR-TB patients started on second-line treatment in the reporting period.</p>	<p>Poltavska obl - 275, Mykolayivska obl- 313 (2014, NTP)</p>	<p>Poltavska obl - 300, Mykolayivska obl- 350 by regimens: 20 for shortened regimens, 5 pre/XDR patients with new drugs</p>	<p>Poltavska oblast: 280 Mykolayivska oblast: 488 (Oct–Sept 2016)</p>
3. 2. 7	Number and percent of MDR-TB cases successfully treated	<p>Description: The proportion of confirmed MDR-TB patients successfully treated (cured plus completed treatment) among those enrolled on second line TB treatment during the reporting period (where applicable disaggregation by HIV status, XDR status). RR-TB may fall under confirmed MDR-TB depending on the country's MDR-TB diagnosis algorithm.</p> <p>Indicator Value: Percent.</p> <p>Level: National and Challenge TB geographic areas.</p> <p>Numerator: Number of confirmed MDR-TB cases successfully treated (cured plus completed treatment).</p> <p>Denominator: Total number of confirmed MDR-TB patients enrolled on second line TB treatment during the reporting period.</p>	<p>Poltavska obl - 102 (53%), Mykolayivska obl- 41 (37%) (2014, NTP cohort 2012)</p>	<p>Poltavska obl - 55%, Mykolayivska obl- 42%</p>	<p>Poltavska obl – 67 (38%) (Treatment success rate decreased comparing to the 2012 cohort because in 2013 all “chronic” pre-XDR patients, who received just palliative care, were enrolled into the treatment)</p> <p>Mykolayivska obl – 176 (58%) (NTP cohort 2013)</p> <p>Official 2014 cohort data will be available in the middle 2017.</p>

3.2.12	% of HIV-positive registered TB patients given or continued on anti-retroviral therapy during TB treatment	Description: The purpose is to measure commitment and capacity of TB service to ensure that HIV-positive TB patients are able to access ART. This indicator measures people registered as HIV-positive who started TB treatment and who also started or continued on ART (i.e. recorded in ART register). Indicator Value: Percent. Level: National and Challenge TB geographic areas. Numerator: All HIV-positive TB patients, registered over a given time period, who receive ART (are started on ART). Denominator: All HIV-positive TB patients registered over the same given time period.	Poltavska obl - 64%, Mykolayivska obl- 63% (2014, NTP)	Poltavska obl - 65%, Mykolayivska obl- 65%	Poltavska obl - 65%, Mykolayivska obl- 58% (APA2, preliminary data. Data will be finalized in Jan 2017)
3.2.24	% MDR patients who receive social or economic benefits	Description: Proportion of TB patients who receive any social or economic benefits (defined as tangible support through interventions delivering services, psycho-emotional support, material goods and/or financial assistances) during the first month of second-line drug (SLD) treatment. Indicator Value: Percent. Level: National and Challenge TB geographic areas. Numerator: Number of MDR-TB patients who receive any social or economic benefits during the first month of SLD treatment. Denominator: Total number of MDR-TB patients initiating SLD treatment during the reporting period.	0	20%	30% (224/755) Poltavska obl. – 26% (96/259) Mykolayivska obl. – 37% (128/496)

Objective 2. Prevention

Sub-objective 5. Infection control

To ensure compliance with proper IC measures in all health care settings and in the community, CTB project provided assistance in project oblasts in implementation of the developed facility and oblast IC plans, developed 2 brochures on UV lams and personal protection equipment, and procured essential IC equipment (UV lamps, respirators and masks) for two oblasts.

Figure 6. UV lamps and PPE brochures.



#	Outcome Indicators	Indicator Definition	Baseline (Year/ timeframe)	Target Y2	Result Y
5.1.1	Status of TB IC implementation in health facilities	Description: This indicator measures the status of TB IC implementation in health facilities. Indicator value: Score based on below: 0=no TB IC policy/plan and no organized TB IC activities; 1=national TB IC guidelines have been approved and disseminated in accordance with WHO policy; 2=TB IC being implemented in pilot or limited health facilities; 3=TB IC implemented nationally and/or national certification program implemented	2	2	2
5.2.3	Number and % of health care workers diagnosed with TB during reporting period	Description: This indicator measures the percent of healthcare workers (HCWs) diagnosed with TB (all forms) annually (disaggregated by gender and age). This measurement may require a special study using a validated tool and/or methodology. Indicator Value: Percent. Level: National and Challenge TB geographic areas.	Poltavska obl – 0.04% (11/26,085) Mykolayivska obl- 0.04% (8/18,508) (2014, NTP)	Poltavska obl - 10, Mykolayivska obl- 7	Poltavska obl – 0.03% (8/26,424) Mykolayivska obl – 0.08% (15/18,144)

		Numerator: Number of HCWs diagnosed with TB (all forms) during past year. Denominator: Total number of HCWs in the same year.			
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Objective 3. Strengthened TB Platforms

Sub-objective 7. Political commitment and leadership

Intervention area 7.1. Endorsed, responsive, prioritized and costed strategic plan available.

7.1.1. National TB Control program development for (NSP) 2017 – 2021:

To ensure sustainability of effective TB-related interventions at the national and oblast levels, and to enable the government of Ukraine to make critical, technically sound policy and program decisions to improve TB control in accordance with international best practices, the CTB project provided technical assistance to the NTP and MOH in development of the next national TB strategic plan (program) for 2017–2021 based on the WHO NTP review conducted in April 2015. At the request of the NTP, two project staff participated in the working groups on draft program development. Currently the draft program is ready and financial background is also finalized. The next step will be approval of the developed program as the National Law according to the legislation of Ukraine. It is extremely important to finalize the program during the nearest month to ensure timely and proper funding of TB activities in 2017.

#	Outcome Indicators	Indicator Definition	Baseline (Year/ timeframe)	Target	Result
				Y2	Y
7. 1. 2	Status of NSP development: 0=The NSP is expired or not being implemented; 1=An updated/new NSP is being drafted; 2=NSP has been developed and costed; 3=NSP has been finalized, endorsed by the government and implemented	Description: This indicator measures the status of NSP development. Indicator value: Score based on below: 0=The NSP is expired or not being implemented; 1=An updated/new NSP is being drafted; 2=NSP has been developed and costed; 3=NSP has been finalized, endorsed by the government and implemented. Level: National.	0	2	2

Sub-objective 11. Human resource development

During the reporting period, the project officially handed over the training Curricula on MDR–TB case management developed during the APA1 to the NTP and all partners. This Curricula is used

Figure 7. MDR-TB Training



for trainings by all projects in the country including GF grant and STBCU.

To strengthen the capacity of TB providers at the oblast level in MDR-TB case management the project conducted one training for **21 TB providers** from Mykolayivska, Poltavaska and Kyivska oblasts. Now all TB providers from Poltavaska and Mykolayivska oblasts have been trained by the CTB project. Given that Kyivska oblast was enrolled into the project in the middle of the reporting period two additional training are needed to make

all TB providers trained.

Overall **125 PHC providers** were trained during 6 trainings to enhance their TB management skills, help promote patient-centered care, and equip providers with skills and strategies to improve treatment adherence.

#	Outcome Indicators	Indicator Definition	Baseline (Year/ timeframe)	Target	Result
				Y2	Y
11 .1 .3	# of healthcare workers trained, by gender and technical area	Description: This indicator measures the number of healthcare workers (which includes health facility staff, community health volunteers, laboratory staff, sputum transport technicians, community-based DOTS workers) trained, by gender and sub-objective. Training includes any in-person, virtual, or on-the-job training that is longer than half a day and for which curriculum is available. This indicator is interchangeable with 'Number of individuals trained in any component of the WHO Stop/End TB Strategy with USG funding' which USAID missions may have as a requirement for internal agency reporting.	80	100	219 (59 M/ 160 F)

		<p>Indicator Value: Number. Level: National and Challenge TB geographic areas.</p> <p>Numerator: Number of HCWs trained during the reporting period.</p>			
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4. Challenge TB Support to Global Fund Implementation

Name of grant and principal recipient (<i>i.e.</i> , TB NFM - MoH)	Average rating*	Current rating	Total signed amount	Total committed amount	Total disbursed to date
Joint TB/HIV Grant (3 PRs)	B1	B1	US\$132,922,178	\$117,656,202	\$84,495,351
PR: INTERNATIONAL HIV/AIDS ALLIANCE, UKRAINE	n/a	n/a	US\$66,268,901	\$59,397,538	\$45,731,420
PR: ALL-UKRAINIAN NETWORK OF PEOPLE LIVING WITH HIV/AIDS	n/a	n/a	US\$63,279,884	\$55,477,332	\$36,698,875
PR: UKRAINIAN CENTER FOR SOCIALLY DANGEROUS DISEASE CONTROL OF THE MINISTRY OF HEALTH (UCDC)	B1	B1	US\$3,373,393	\$2,781,332	\$2,065,056

* Since January 2010

In-country Global Fund status – key updates, current conditions, challenges and bottlenecks

Ukraine is currently implementing a joint TB and HIV grant for 2015–2017, which combines the activities included in an HIV Round 10 proposal and a TB Round 9 proposal. The grant is being managed by three principal recipients: The Ukrainian Center for Socially Dangerous Disease Control (UCDC) of the Ukraine MOH, All-Ukrainian Network of People Living with HIV/AIDS (PLWHA Network), and International HIV/AIDS Alliance in Ukraine.

The single TB and HIV concept note for 2015–2017 focuses on the further alignment of HIV and TB in relation to leadership and governance, financing, information systems, the health workforce, service delivery, and community systems. It includes interventions for the provision of defined service packages for injection drug users (IDUs), commercial sex workers (CSWs), men who have sex with men (MSM), and prisoners; HIV testing and counseling; a condom program; HIV treatment, care, and support; and MDR-TB treatment.

The current concept note is expected to partially fill the weaknesses and gaps of the state-funded National AIDS Program 2014–2018 and the NTP 2012–2016. The goal of the three-year grant is to contain the TB and HIV epidemics and reduce TB- and HIV-related morbidity and mortality in Ukraine. Given the concentrated nature of the epidemics, the focus is on IDUs, CSWs, MSM, and the transgender population; TB-infected people and their contacts; PLWHA and the sexual partners of most-at-risk populations (MARPs) and PLWHA; and the prison population.

Thus, the concept note states the following three objectives for the proposed program:

1. To scale up and ensure equitable access to high-quality TB and HIV prevention, treatment, care, and support with a focus on key affected populations (MARPs, PLWHA, and other people most affected by the HIV and TB epidemic).
2. To strengthen the health system toward sustainable and integrated solutions for key populations most affected by the HIV and TB epidemic.

3. To strengthen community systems that enable needs-based, cost-effective, and integrated interventions for key populations most affected by the HIV and TB epidemic.

Initially, technical assistance to improve the TB response was nearly omitted from the grant. The grant focused activities on the procurement of second-line drugs and diagnostic supplies. It included minimum support for capacity-building and technical assistance in other areas. The work plan was later revised to strengthen technical assistance to TB providers, including capacity-building and patient support during treatment. A plan to create six centers to conduct trainings for TB providers was introduced to, and approved by, the Global Fund.

Integration of TB services into the primary health care system is not included in grant implementation, and the comprehensive ambulatory case management approach will not be directly strengthened under this grant.

To ensure support to patients for treatment adherence, two grant sub-recipients have been identified and approved: the PLWHA Network, to support patients with drug-sensitive TB, and the Ukrainian Red Cross, to support patients with MDR-TB. MDR-TB patients receiving treatment under the Global Fund grant (approximately 35 percent of all MDR-TB patients) will be supported by the Ukrainian Red Cross. Patients with drug-sensitive TB will be supported by the PLWHA Network. The State Penitentiary Service of Ukraine was approved as the sub-recipient for TB case management activities in prisons, as it was defined in the grant concept note.

In general, the grant is being implemented as scheduled. Currently the rating of the grant is B1. Nevertheless, there are certain conditions (the main one is that Ukraine will start procurement of substitutional therapy drugs for the governmental funding and will ensure sustainability of the procurement services) that the Global Fund raised several times to the government, which, if not being implemented, would lead to budget reduction by 15 percent.

In 2016, Global Fund principal recipients reported the substantial savings of funding totaling \$13.392 million. These savings have been re-programmed according to the needs of TB and HIV programs to ensure uninterrupted diagnosis and treatment of patients through the end of the grant period (end of 2017). The TB program will receive \$6.103 million, including second-line drugs procurement of \$5.728 million and support of patients with drug-sensitive TB of \$0.375 million.

Challenge TB involvement in Global Fund support/implementation and any actions taken during Year 2

During the reporting period, the CTB project team participated in a number of meetings and consultant communications with the MOH, UCDC, a Global Fund consultant, and other stakeholders on the development of the transition plan for governmental funding of activities currently funded by Global Fund to ensure sustainability of the provided services. Based on the results of the working group discussions, the “Strategy on the sustainable response to TB, MDR-TB and HIV/AIDS epidemic, and implementation work plan approval” was developed and

endorsed by the Cabinet of Ministers; three CTB project staff participated in the working group and provided feedback and recommendations that have been considered. The plan contains a table of risk assessment of the transition process, strategic prioritization approach, progressive transition plan, and other documents. The strategy recognized the obvious need for Ukraine to receive an additional Global Fund grant to ensure sustainability and avoid gaps in treatment and diagnostic quality.

The CTB staff member became a member of the Program Committee of the National Coordination Council (CCM) and directly influenced the discussions and decisions on grant implementation.

At the regional level, the CTB project monitored the support provided to drug-sensitive TB patients by regional PLHIV Network organizations. The Global Fund grant funds these organizations with the goal of improving and ensuring treatment completion. In practice, very few patients are actually being supported and, although TB drugs are distributed, directly observed treatment (DOT) is not always ensured. CTB noted gaps in the quality and reach of support and shared this concern with the UCDC for quality improvement actions and with the USAID Mission. The situation was discussed by CTB staff with the UCDC and local governments as well as with PLHIV Network grantees at the oblast level to increase the role of primary health care providers in DOT assurance.

Finally, the CTB project team conducted meetings with Ukrainian Red Cross regional units and TB Services to discuss the selection of patients participating in MDR-TB activities to avoid overlapping with the Global Fund grant. As was reflected in the plan, the CTB project supports MDR-TB patients who receive treatment with NTP-procured drugs through the Red Cross. Thorough selection of patients is conducted and monitored to avoid duplication with the Global Fund-supported patients.

5. Challenge TB Success Story

Patient Support Helps Treatment Adherence

During the intensive phase of multi-drug resistant TB (MDR-TB) treatment, patients in Poltavs'ka Oblast, Ukraine, are treated in hospitals, and then continue their treatment at outpatient facilities close to their homes.

"I am so grateful for help. Without Nataliya I would not survive"

Serhiy Sysiuk, MDR-TB patient

Treatment success depends on patients adhering to the long course of MDR-TB treatment, which is influenced by the of different factors of a patient's life. In many cases, patients feel helpless as they face numerous serious problems after leaving the hospital and are at risk to stop taking their medication. That is why knowing a patient's needs and providing constant support to them and their families in a way that is respectful and responsive to their preferences, needs and values, can greatly improve treatment success.

After completing the intensive phase of MDR-TB treatment, Serhiy Sysiuk was discharged from hospital. He was supposed to continue outpatient treatment in the Myrhorod Central Rayon Hospital, not far from his home, but he was injured at work and as the result is disabled. He can only walk with crutches, so it was hard for him to get to the health care facility by himself for daily directly observed treatment (DOT). To make matters worse, his elderly mother got very sick and needed round the clock care. Serhiy is divorced, requires substantial help around the home, all of which made him feel hopeless and he thought he would never get well again.

Figure 8. Nataliya Galibina provides Serhiy with grocery store vouchers to improve his treatment adherence.

The USAID funded Challenge TB project hired the local community-based organization "Light of Hope" to provide psychosocial support to MDR-TB patients during the outpatient phase of treatment. So far, the organization has provided support to 96 MDR and extensively-drug resistant TB patients.

Social worker Nataliya Galibina has provided comprehensive care to Serhiy, since December 2015. She convinced the Myrhorod State Center of Social Services to get him a wheelchair and funding for a specialized car, so he could get to the DOT-facility for treatment. They helped to place his mother in the nursing home, and when she died, they also helped with the funeral. The social worker visits Serhiy twice a week to help him with housework and to prepare food. He is provided with the grocery store vouchers to buy food and has a psychologist to help him work through any problem. "Light of Hope" is also trying to get him back in touch with his daughter who stayed with his ex-wife after their divorce.



Serhiy is currently managing to stick to his treatment regime and is determined to get cured. He is grateful for the help received from the project, and has high hopes for the future.

6. Key Challenges during Implementation and Actions to Overcome Them

Challenge	Actions to overcome challenges
Technical	
During a few months of the reporting period, Ukraine lacked second-line drugs procured by the government, although government procurement of new drugs occurred earlier this year. The supply of newly procured drugs started only in August and the full scheme was not supplied as of by the end of September. To avoid treatment gaps, Ukraine used medicines received under the Global Fund grant, which were intended to treat only 50 percent of patients. This means that Ukraine runs the risk of stock outs by the end of the year, if replacement supplies are not received in time.	Given that these procurement problems have occurred above the NTP level, the CTB project closely monitored the situation to ensure that drugs are available for the full treatment course for newly enrolled patients in project sites and advocated for thorough monitoring at the national level.
Rotations of the Minister of Health, the Deputy Ministers in charge of HIV and TB, and the Head of the MOH Public Health department, along with transition of the UCDC into the National Public Health Center, required permanent advocacy and education at all levels of TB control to ensure constancy in understanding and attention to TB control. These changes delayed the approval of the national-level documents, including the earlier submitted protocol on side-effect management developed by the project, and the newly developed draft protocol on the new TB drugs introduction.	To address this challenge, the project implemented strong advocacy at all levels and involved all partners to ensure pressure on the key authorities to prioritize TB care.
Based on the drug-resistance data analysis in the pilot region and a national drug-resistance survey, the data suggested high levels of resistance to the first- and second-line drugs among rifampicin-resistant TB cases (to E 41.8%, Z 34.5%, Oxf 17%, Mxf 8%, Km 6%, and Cm 15% in Kyivska oblast). Taking into account the World Health Organization (WHO) recommendations, under which only patients with the preserved susceptibility to all drugs in the regimen (except for H) may be prescribed shortened treatment regimens, only 46% of patients in the pilot region may apply for the shorter regimens. An additional challenge is the unavailability of clofazimine for procurement in Ukraine (this medicine is not currently	To address this challenge in Ukraine, the project in consultation with national and international experts proposed to adjust the shortened regimens recommended by WHO. The project requested review of suggested regimens from WHO and Green Light Committee (GLC) and will act according to the recommendations.

registered in Ukraine and thus is not available at the pharmaceutical market).	
The most significant challenges in TB contact investigation and management are: the lack of holistic guidelines on TB contact investigation and management; the lack of current, approved guidelines in pediatric TB management; and the current decline of the Sanitary – Epidemiological Services (SES), which used to play a central role in contact investigation and management.	The project team worked with oblast partners to understand the new roles and responsibilities at oblast level that replace the previous scope of the SES.
Administrative	
APA3 planning discussion with USAID, PMU, KNCV and PATH was held in the second half of July, leaving only 1 week for the work plan and budget development. Such timeframe is not appropriate given number of internal reviews and approvals needed for the final work plan to be sent out in PATH and KNCV.	PMU may consider setting APA4 discussions in June.
Amount of cumulative obligations for CTB Ukraine was not finalized with PATH and USAID until mid-July 2016. This created misunderstanding during APA3 budgeting and budget forecasting to USAID Ukraine.	With the help of USAID Ukraine, PMU and AOR, this issue was resolved.

7. Lessons Learnt/ Next Steps

The CTB project work is implementing during a time of major political and military instability in the country, with almost all of key government stakeholders replaced during the last year of project implementation. In addition to the challenges listed above, we encountered other issues as outlined below and developed recommendations that could help to further improve Ukraine's MDR-TB case management.

There are several specific barriers to implementing ambulatory care for MDR-TB and introduction of NDR and the shorter MDR-TB treatment regimen in Ukraine:

- Introduction of NDR and the shorter MDR-TB treatment regimen requires **political will** and pressure for adjusting normative documents and legislative environment. It takes more CTB project time and efforts to promote introduction of NDR in Ukraine.
- Introduction of NDR and the shorter MDR-TB treatment regimen requires **routine access to fast laboratory diagnosis and drug susceptibility testing** to the first and second line drugs including molecular genetic methods like HAIN test.
- The most significant challenges in **TB contacts investigation** and management are: the current decline of the Sanitary – Epidemiological Services (SES), which used to play a

central role in contacts investigation and management; the lack of holistic guidelines on TB contact investigation and management; and the lack of current, approved guidelines in pediatric TB management.

- **Stigma:** MDR-TB is highly stigmatized in Ukraine, particularly among health care providers who are not TB specialists. These include family care doctors, primary health care nurses, and staff from social service organization who should be the main points of contact for MDR-TB patients on ambulatory care. While a portion of the stigma and discrimination can be traced to fear of infection, a larger portion is attributable to the perception that MDR-TB patients are “difficult to work with”—they have comorbid conditions such as drug or alcohol use, have psychological issues, or are homeless—and health providers are poorly equipped to address those issues. Stigma in the community was identified as significant barrier in contact investigation algorithm application.
- **Disincentives for discharge from the hospital:** Traditionally, MDR-TB patients were hospitalized in TB-specialized facilities for long periods of time, sometime until completion of treatment. Although the recently issued protocol stipulates that MDR-TB patients should be discharged from inpatient services as soon as sputum smears are negative (at approximately three to four months), doctors routinely keep patients hospitalized for an average of eight months. There are three main reasons why long hospitalizations continue to be the norm. First, doctors are concerned that patients will be lost to follow-up soon after discharge and therefore prefer to treat them as inpatients for longer periods. Second, hospital staffing and compensation continues to be calculated based on the number of inpatient bed-days. To preserve staff and funding, they may keep patients longer than necessary. Third, patients often need support to continue treatment at outpatient settings, including food, transportation costs, and/or a place to stay overnight. Full implementation of the developed by CTB project patient centered approach, including outpatient treatment model, requires considerable effort and a rethinking of alternative incentives for hospitals to discharge patients.
- **Lack of training:** Primary care providers are not yet well equipped to provide the complex services required for adequate care, especially side-effects management and monitoring of people with MDR-TB. Social service providers in the country are also unprepared to support the needs of MDR-TB patients throughout their long treatment and need sufficient capacity building efforts.
- On the positive note, the CTB project learnt that **patient centered approach** based on ambulatory care model, when properly designed, introduced and comprehensively managed and monitored is well received by providers in Ukraine and allow to improve treatment outcomes significantly.
- ADRs during MDR-TB treatment, being the main barrier for treatment completion were poorly managed especially during the outpatient treatment stage. Results of APA2 reveal

that proper guidelines, capacity building of providers, system strengthening and appropriate availability of laboratory supplies for ADR diagnostic and drugs for management can significantly enhance the overall ADR prevention and management and thus lead to treatment adherence.

Next steps:

In the third year, the CTB plans activities at three levels: 1) project activity level, 2) dissemination level, and 3) national level. The project will be implementing activities under six objectives: 1) active case finding of close contacts of TB and MDR-TB patients; 2) improving quality of MDR-TB services; 3) expanding outpatient services for TB and MDR-TB patients; 4) introducing new drug regimens and medicines for MDR-TB; 5) conducting TB/HIV collaborative activities; and 6) developing human resources, disseminating best practices, developing policy and conducting advocacy. The implementation will cover seven oblasts—namely Kyivska, Lvivska, Kharkivska, Dnipropetrovska, Poltavska, Mykolayivska, and Odesska—which will be considered as pilot regions of implementation. Of these pilot regions, four oblasts (Kyivska, Kharkivska, Lvivska, and Dnipropetrovska) will be designated as technical assistance hubs (TA hubs). In addition to implementing project activities around TB case detection, treatment, and control within their own geographical dominions, the hubs will provide TA to neighboring oblasts. As Kyivska oblast is already an implementing site, third-year activities there will continue alongside its new role as TA hub. The purpose of the TA hubs is to capitalize on the respective strengths of these regions as well as to learn lessons from implementation in order to provide leadership and support to other regions. This will include capacity development, propagation of best practices to other regions, and engagement in advocacy for resource mobilization along with influencing the adoption of new policies. To ensure that the hub activities don't affect the implementation of detection, treatment, and control activities within the same region, around 80 percent of the efforts will be invested in the implementation while the remaining 20 percent will be devoted to hub activities. Odesska, Poltavska, and Mykolayivska oblasts will remain as implementation sites only.

Taking all of this information into account, the following steps are recommended to move the primary health care MDR-TB case management agenda forward:

1. Assess systems and services in the new CTB project sites.
2. Conduct intensive engagement with government and all care providers, including the private and public sectors, business and civil society, and professional and community-based groups, in the new sites to ensure patient centered approach and to strengthen response to TB.
3. Pay attention to issues that remain major barriers to progress.
4. Convene technical partners and government staff working on ambulatory care to ensure coordination across efforts.
5. Introduce and extend the NDR and the shorter MDR-TB treatment regimen in the project oblasts.

6. Develop Hub strategy and disseminate TA to the neighboring oblasts.
7. Educate partners and stakeholders when needed to obtain their support.
8. Provide technical assistance to set up systems ensuring the quality and continuity of care provided in both inpatient and outpatient settings through supervision visits with onsite coaching, an analysis of findings, and solution development.
9. Support institutionalization, implementation, and evaluation of developed ambulatory care models in the new oblasts. Support collection and analysis of data on key affected populations as part of this process to refine approaches.
10. Assess and improve infection control at all stages of MDR-TB case management at the oblast level as needed.
11. Implement PEPFAR funded TB/HIV activities.
12. Convene quarterly meetings of stakeholders at the oblast level to discuss progress and problem-solve challenges.
13. Convene an annual conference of oblasts implementing ambulatory care for MDR-TB patients to foster cross-program learning and identify best practices.

Annex I: Year 2 Results on Mandatory Indicators as well as National Data on the Number of pre-/XDR-TB Cases Started on Bedaquiline or Delamanid

MANDATORY Indicators				
<i>Please provide data for the following mandatory indicators:</i>				
2.1.2 A current national TB laboratory operational plan exists and is used to prioritize, plan and implement interventions.	National APA 2	CTB APA 2	CTB APA 2 investment	Additional Information/Comments
Score as of September 30, 2016	0	N/A	None	There is no consistent Laboratory Operational Plan (LOP) in the Ukrainian NTP. NTP 2012-2016 contains essential elements of the LOP: Lab optimization plan, new diagnostic tools introduction and implementation, procurement of Lab consumables, TB microscopy/culture EQC, HR capacity building, but doesn't include strategy and management principles.
2.2.6 Number and percent of TB reference laboratories (national and intermediate) within the country implementing a TB-specific quality improvement program i.e. Laboratory Quality Management System	National APA 2	CTB APA 2	CTB APA 2 investment	Additional Information/Comments

Number and percent as of September 30, 2016	0% (0/33)	N/A	None	Currently, there is one national reference laboratory (NRL) functioning in Ukraine; there are 24 Level-3 labs (one in each region) in the civil sector and 8 Level-3 labs in the penitentiary system. Neither the NRL or intermediate-level laboratories (32 Level-3 labs that perform culture and DST) are accredited using the international regulations under ISO15189. Neither the "Global Laboratory Initiative (GLI) Stepwise Process towards TB Laboratory Accreditation" (scoring = phase 1-4) nor SLIPTA/SLMTA for TB (scoring=stars 1-5) were implemented in Ukraine.
2.2.7 Number of GLI-approved TB microscopy network standards met	National APA 2	CTB APA 2	CTB APA 2 investment	Additional Information/Comments
Number of standards met as of September 30, 2016	9	N/A	None	The standard numbers that are met: 1,2,3,5,6,7,9,10,11

2.3.1 Percent of bacteriologically confirmed TB cases who are tested for drug resistance with a recorded result.	National 2015	CTB 2015	CTB APA 2 investment	Additional Information/Comments
Percent (new cases) , include numerator/denominator	96.8% (13,421/13,860)	97% (1,510/1,557)	None	CTB did not invest here directly. Indirectly we influence this indicator through MDR-TB case management trainings, site visits etc.
Percent (previously treated cases) , include numerator/denominator	95.2% (7,630/8,015)	97.3% (944/970)		
Percent (total cases) , include numerator/denominator	96.2% (21,051/21,875)	97.1% (2,454/2,527)		
3.1.1. Number and percent of cases notified by setting (i.e. private sector, pharmacies, prisons, etc.) and/or population (i.e. gender, children, miners, urban slums, etc.) and/or case finding approach	National APA2	CTB APA2	CTB APA 2 investment	Additional Information/Comments
Number and percent	<i>Fill in data in "Ind 3.1.1 - APA 2" worksheet</i>	<i>Fill in data in "Ind 3.1.1 - APA 2" worksheet</i>	Limited	
3.1.4. Number of RR-TB or MDR-TB cases notified	National APA 2	CTB APA 2	CTB APA 2 investment	Additional Information/Comments
Total 2015	8,440	745	Limited	
Jan-Mar 2016	2,481	177		
Apr-June 2016	2,493	192		
Jul-Sept 2016	2,051	189		
To date in 2016	7025	558		
3.2.1. Number and percent of TB cases successfully treated (all forms) by setting (i.e. private sector, pharmacies, prisons, etc.) and/or by population (i.e. gender, children, miners, urban slums, etc.).	National 2014 cohort	CTB 2014 cohort	CTB APA 2 investment	Additional Information/Comments

Number and percent of TB cases successfully treated in a calendar year cohort	Getting from WHO	745 (69%) - Mykolayivska obl; 651 (74%) Poltavaska obl	Limited	WHO data: New and relapse cases registered in 2014 - 72% (cohort 22 294) Previously treated cases, excluding relapse, registered in 2014 - 66% (cohort 5,269) HIV-positive TB cases, all types, registered in 2014 - 35% (cohort 6,104)
3.2.4. Number of patients started on MDR-TB treatment	National APA 2	CTB APA 2	CTB APA 2 investment	Additional Information/Comments
Total 2015	8,411	676	Moderate	
Jan-Mar 2016	2,453	182		
Apr-June 2016	2,479	191		
Jul-Sept 2016	2,028	186		
To date in 2016	6,960	559		
3.2.7. Number and percent of MDR-TB cases successfully treated	National 2013 cohort	CTB 2013 cohort	CTB APA 2 investment	Additional Information/Comments
Number and percent of MDR-TB cases successfully treated in a calendar year cohort	2,948 (39%) (cohort 7,633)	58% (176) - Mykolayivska oblast 38% (67) - Poltavaska oblast	Substantial	
5.2.3. Number and % of health care workers diagnosed with TB during reporting period	National 2015	CTB 2015	CTB APA 2 investment	Additional Information/Comments
Number and percent reported annually	0.06% (399/688,643)	0.08% (15/18,144) - Mykolayivska oblast 0.03% (8/26,424) - Poltavaska oblast	Limited	
6.1.11. Number of children under the age of 5 years who initiate IPT	National 2015	CTB 2015	CTB APA 2 investment	Additional Information/Comments
Number reported annually	10,054	364 - Mykolayivska oblast 284 - Poltavaska oblast	None	NTP data is for children 0-14 only.
7.2.3. % of activity budget covered by private sector cost share, by specific activity	National APA 2	CTB APA 2	CTB APA 2 investment	Additional Information/Comments

Percent as of September 30, 2016 (include numerator/denominator)	N/A	N/A	None	CTB did not collaborate with the private sector. The current landscape in Ukraine does not lend itself to private-sector participation.
8.1.3. Status of National Stop TB Partnerships	National APA 2	CTB APA 2	CTB APA 2 investment	Additional Information/Comments
Score as of September 30, 2016	0	N/A	None	There is no STOP TB Partnership in Ukraine.
8.1.4. % of local partners' operating budget covered by diverse non-USG funding sources	National APA 2	CTB APA 2	CTB APA 2 investment	Additional Information/Comments
Percent as of September 30, 2016 (include numerator/denominator)	N/A	78.7% (780,224.7/990,797.2)	Moderate	57.8% Initiative for life 78.3% Light of hope 94.6% Vykhid 73.3% URC Mykolayiv 79.1% URC Poltava
8.2.1. Global Fund grant rating	National APA 2	CTB APA 2	CTB APA 2 investment	Additional Information/Comments
Score as of September 30, 2016	B1	N/A	None	In January 2015, Ukraine started to implement a joint TB/HIV grant for 2015–2017, which combined the activities included in an HIV Round 10 proposal and a TB Round 9 proposal for which the latest rates were A1 and B1, respectively.
9.1.1. Number of stock outs of anti-TB drugs, by type (first and second line) and level (ex, national, provincial, district)	National APA 2	CTB APA 2	CTB APA 2 investment	Additional Information/Comments

Number as of September 30, 2016	U	U	None	There are delays of delivery of drugs procured using government funds. Regions are currently experiencing the lack of kanamycin and capreomycin. UCDC redistributes drugs between regions to mitigate the issue and to avoid treatment interruptions. Mykolaiv region did not report TB drugs stock outs in APA2. Poltava region reported second line TB drugs stock outs resulted in delayed treatment starts (patients treatment waiting list).
10.1.4. Status of electronic recording and reporting system	National APA 2	CTB APA 2	CTB APA 2 investment	Additional Information/Comments
Score as of September 30, 2016	3	N/A	Limited	ERR is a patient/case-based, realtime system that functions at national and subnational levels for both TB and MDR-TB.
10.2.1. Standards and benchmarks to certify surveillance systems and vital registration for direct measurement of TB burden have been implemented	National APA 2	CTB APA 2	CTB APA 2 investment	Additional Information/Comments

Yes or No as of September 30, 2016	No	N/A	None	Ukrainian surveillance and vital registration systems were assessed in 2015 within the WHO NTP review with application of standards and benchmarks instrument. Results and recommendations are ready and will be provided to NTP along with assessment report. Out of 12 standards for TB surveillance applicable for Ukraine, 4 were met, 6 were partially met, and 2 were not met (2015, NTP Review).
10.2.6. % of operations research project funding provided to local partner (provide % for each OR project)	National APA 2	CTB APA 2	CTB APA 2 investment	Additional Information/Comments
Percent as of September 30, 2016 (include numerator/denominator)	N/A	N/A	None	The CTB project did not conduct an operational research during APA2.
10.2.7. Operational research findings are used to change policy or practices (ex, change guidelines or implementation approach)	National APA 2	CTB APA 2	CTB APA 2 investment	Additional Information/Comments
Yes or No as of September 30, 2016	N/A	N/A	None	The CTB project did not conduct an operational research during APA1 and APA2.
11.1.3. Number of health care workers trained, by gender and technical area	CTB APA 2		CTB APA 2 investment	Additional Information/Comments

			Substantial	CTB included Kyivska oblast specialists into trainings to improve PMDT and build capacity for NDR implementation. Kyivska oblast was identified as a pilot site for NDR and shorter treatment regimens introduction.
	# trained males APA 2	# trained females APA 2	Total # trained in APA 2	Total # planned trainees in APA 2
1. Enabling environment			0	
2. Comprehensive, high quality diagnostics			0	
3. Patient-centered care and treatment	59	160	219	170
4. Targeted screening for active TB			0	
5. Infection control			0	
6. Management of latent TB infection			0	
7. Political commitment and leadership			0	
8. Comprehensive partnerships and informed community involvement			0	
9. Drug and commodity management systems			0	
10. Quality data, surveillance and M&E			0	
11. Human resource development			0	
Other (explain)			0	
Other (explain)			0	
Grand Total	59	160	219	170
11.1.5. % of USAID TB funding directed to local partners	National APA 2	CTB APA 2	CTB APA 2 investment	Additional Information/Comments
Percent as of September 30, 2016 (include numerator/denominator)	N/A	5% (86,238/1,830,973)	Moderate	Same 5 NGOs listed under 8.1.4 above

Year/Quarter	Number of pre-/XDR-TB cases started on BDQ nationwide	Number of pre-/XDR-TB cases started on DLM nationwide	CTB APA 2 investment	Additional Information/Comments
Total 2014	0	0	Limited	Both BDQ and DLM are not introduced in the country yet.
Total 2015	0	0		
Jan-Mar 2016	0	0		
Apr-Jun 2016	0	0		
Jul-Aug 2016	0	0		
To date in 2016	0	0		

		Reporting period					CTB APA 2 investment
		Oct-Dec 2015	Jan-Mar 2016	Apr-Jun 2016	Jul-Sept 2016	Cumulative Year 2	
Overall CTB geographic areas	TB cases (all forms) notified per CTB geographic area (<i>List each CTB area below - i.e. Province name</i>)						None
	Poltavska	291	276	284	262	1,113	
	Mykolayivska	333	320	326	298	1,277	
						0	
						0	
						0	
						0	
						0	
						0	
	TB cases (all forms) notified for all CTB areas	624	596	610	560	2,390	
	All TB cases (all forms) notified nationwide (denominator)	8,448	9,265	8,913	7,781	34,407	

	% of national cases notified in CTB geographic areas	7%	6%	7%	7%	7%	
Intervention (setting/population/approach)							CTB APA 2 investment
Contact investigations	CTB geographic focus for this intervention	Poltavska, Mykolayivska					Limited
	TB cases (all forms) notified from this intervention	16	8	10	14	48	
	All TB cases notified in this CTB area (denominator)	624	596	610	560	2,390	
	% of cases notified from this intervention	3%	1%	2%	3%	2%	

Annex II: Status of EMMP activities

Year 2 Mitigation Measures	Status of Mitigation Measures	Outstanding issues to address in Year 3	Additional Remarks
Education, technical assistance and training about activities that inherently affect the environment include discussion prevention and mitigation of potential negative environmental effects.	CTB ensured transition from the traditional participation on training invents with transportation which potentially affect the environment to a distant educational approaches (webinars etc.).	In Year 2 there were no outstanding issues to be addressed in Year 3.	
CTB ensured proper procurement of audiometers and UV fixtures, which were delivered directly to Poltavaska and Mykolayivska oblasts TB dispensaries. Although the responsibility for proper storage and distribution to the intermediate/peripheral levels lies with the NTP, CTB advised on the proper storage based on the information provided on the manufacturer's Materials Safety Data Sheet as well as WHO's <i>Safe Management of Waste from Health-care Activities</i> (http://www.who.int/water_sanitation_health/medicalwaste/wastemanag/en/).	CTB ensured proper items procurement and delivery. Recipients adhere to country regulation and manufacturer's guidelines.	In Year 2 there were no outstanding issues to be addressed in Year 3.	
Laboratory supplies including reagents and vacuum test tubes were blended into government provided supplies and thus properly disposed following national SOPs based on WHO recommendations for properly dispose of the medical waste by adhering the standard practice of medical waste disposal dictated by the laboratory, which will prevent any harm from the medical waste to the environment. CTB monitors SOPs adherence by project facilities.	During the site visits CTB staff monitored regulations implementation.	In Year 2 there were no outstanding issues to be addressed in Year 3.	